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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,731	10/08/2003	J. Christopher Flaherty	59249-158 (INSL-114DV)	6691

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EXAMINER	
GRAY, PHILLIP A	
ART UNIT	**PAPER NUMBER**
3767	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	**Application No.** 10/681,731	**Applicant(s)** FLAHERTY ET AL.
	Examiner Phillip Gray	**Art Unit** 3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 19 April 2007.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 48-50,52-57,59 and 60 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) 48-50,52-57,59 and 60 is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's remarks and response received on 4/19/2007. Currently amended claims 48-50, 52-57, 59-60 are pending and rejected below.

Response to Arguments

Applicant's arguments filed 4/19/2007 have been fully considered but they are not persuasive. Applicant argues that the addition of the claim language "wherein the skin penetrating member is contained entirely within the housing when the skin penetrating member is in the retracted position, and the infusion cannula is more flexible than the penetrating member" overcomes the prior art of record.

Examiner is of the position that Gross discloses that the skin penetrating member is contained entirely within the housing when the skin penetrating member is in the retracted position. Examiner references figures 13 and 16 of the Gross reference as evidence of this teaching/disclosure. Further examiner is of the position that the cannula of Douglas and Larsen are more flexible then the penetrating members. Examiner draws attention to the description of the Larsen cannula as "flexible" (see Larsen column 5 lines 21-24) and the cannula of Douglas seems to be "flexing" over other elements where the penetrating member is stiff or rigid (see Douglas figures 2 and 3).

Therefore it is examiners position that the newly added amendments do not overcome the prior art of record. It is examiners suggestion that applicant amended the claims to more specifically define the aspect that they consider is novel. The elements disclosed in the prior art of record are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48-50, 52-57, 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al. (U.S. Patent Number 5,997,501) in view of Douglas et al. (U.S. Patent Number 6,685,674).

Gross discloses an interdermal drug delivery device (as in figure 3) with a housing (2) defining a reservoir (10), a dispenser (12) within the housing and operatively coupled to the reservoir, an inlet valve/needle septum (24), a subcutaneous infusion cannula and skin penetrating member (14), and an adhesive layer (309) and a retractable needle with a shapened tip (figures 13,14).

Douglas teaches a device for delivering fluid to a patient, comprising: a housing defining a reservoir; an inlet valve accessible from an exterior of the housing and connected to the reservoir; a subcutaneous infusion cannula extending from the housing, in fluid communication with the reservoir and including a distal tip; and a skin penetrating member movably positioned within the infusion cannula between a retracted position wherein a sharpened tip of the penetrating member is contained within the device and an extended position wherein the sharpened tip of the penetrating member extends from the distal tip of the cannula. (Figures 1-15)

Gross discloses the claimed invention except for the skin penetrating member movably positioned within the infusion cannula. Douglas teaches that it is known to use the skin penetrating member movably positioned within the infusion cannula as set forth in paragraphs at columns 4-6 to provide a smooth and retractable needle penetration operation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the drug delivery device as taught by Gross with the skin penetrating member movably positioned within the infusion cannula as taught by Douglas, since such a modification would provide the drug delivery device with the skin penetrating member movably positioned within the infusion cannula for providing a smooth and retractable needle penetration operation.

Concerning the claim language about the penetrating member containted within the housing and the flexibility of the cannula, examiner is of the position that Gross discloses that the skin penetrating member is contained entirely within the housing when the skin penetrating member is in the retracted position. Examiner references figures 13 and 16 of the Gross reference as evidence of this teaching/disclosure. Further examiner is of the position that the cannula of Douglas is more flexible then the penetrating members. Examiner draws attention to the description of Douglas seems to be "flexing" over other elements where the penetrating member is stiff or rigid (see Douglas figures 2 and 3).

Claims 48-50, 52-57, 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al. (U.S. Patent Number 5,997,501) in view of Larsen et al. (U.S. Patent Number 5,968,011).

Gross discloses an interdermal drug delivery device (as in figure 3) with a housing (2) defining a reservoir (10), a dispenser (12) within the housing and operatively coupled to the reservoir, an inlet valve/needle septum (24), a subcutaneous infusion cannula and skin penetrating member (14), and an adhesive layer (309), and a retractable needle with a shapened tip (figures 13,14).

Larsen teaches a device for delivering fluid to a patient, comprising: a housing defining a reservoir; an inlet valve accessible from an exterior of the housing and connected to the reservoir; a subcutaneous infusion cannula extending from the housing, in fluid communication with the reservoir and including a distal tip; and a skin penetrating member movably positioned within the infusion cannula between a retracted position wherein a sharpened tip of the penetrating member is contained within the device and an extended position wherein the sharpened tip of the penetrating member extends from the distal tip of the cannula. (Figures 1-19)

Gross discloses the claimed invention except for the skin penetrating member movably positioned within the infusion cannula. Larsen teaches that it is known to use the skin penetrating member movably positioned within the infusion cannula as set forth in paragraphs at columns 5-8 to provide a smooth and retractable needle penetration operation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the drug delivery device as taught by Gross with the skin penetrating member movably positioned within the infusion cannula as taught by Larsen, since such a modification would provide the drug delivery device with the skin penetrating member movably positioned within the infusion cannula for providing a smooth and retractable needle penetration operation.

Concerning the claim language about the penetrating member containted within the housing and the flexibility of the cannula, examiner is of the position that Gross discloses that the skin penetrating member is contained entirely within the housing when the skin penetrating member is in the retracted position. Examiner references figures 13 and 16 of the Gross reference as evidence of this teaching/disclosure. Further examiner is of the position that the cannula of Larsen is more flexible then the penetrating members. Examiner draws attention to the description of the Larsen cannula as "flexible" (see Larsen column 5 lines 21-24).

Further Claims 48-50, 52-57, 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross, alone.

Gross discloses the claimed invention except for the skin penetrating member movably positioned within the infusion cannula. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the skin penetrating member movably positioned within the infusion cannula, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70 (CCPA 1950), and* it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Newin v. Erlichman, 168 USPQ 177 (BdPatApp&Int 1969)*. The device of Gross has all the operational elements as claimed but simply has the skin penetration element passing through the conduit 308/309. Examiner is viewing this element as fully capable of satisfying all functional, operational, and spatial limitations of the cannula element as in the applicants claim. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The cannula as claimed is intended as a passageway which directs the skin penetration device and medicament. The element conduit of Gross is fully capable of satifiying this intended use and is a structural equivalent.

Concerning the claim language about the penetrating member containted within the housing and the flexibility of the cannula, examiner is of the position that Gross discloses that the skin penetrating member is contained entirely within the housing when the skin penetrating member is in the retracted position. Examiner references figures 13 and 16 of the Gross reference as evidence of this teaching/disclosure.

Gross discloses the claimed invention except for is silent whether the cannula is more flexible then the penetrating member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the cannula made of a more flexible material then the penetrating member, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).* This would allow the penetrating member to more effectively penetrate the target site then the cannula alone would be capable of.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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